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10/712,265	11/14/2003	Nadine Ferdman Burton	051438-5002	8062
9629	7590	06/09/2009	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			TREYGER, ILYA Y	
ART UNIT	PAPER NUMBER			
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06/09/2009	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,265	<b>Applicant(s)</b> BURTON ET AL.
	<b>Examiner</b> ILYA Y. TREYGER	<b>Art Unit</b> 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 February 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 17-28 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-15 and 17-28 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 28 November 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1, 14, 15 and 28 are amended.
2. Claim 16 is canceled.
3. Claims 1-15 and 17-28 are examined on the merits.

*Response to Arguments*

4. Applicant's arguments filed 02/05/2009 have been fully considered but they are not persuasive:
5. With respect to claim 1, Applicants argue that the combination of references does not disclose the claimed invention because the joining piece 30 of Marie is joined by the type of snap fitting that cannot be undone, and therefore the joining piece 30 of Marie can not be considered as removable cap.

However, anything mechanically connected can be disconnected, and therefore any connectable element can be interpreted as a disconnectable element. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the joining piece 30 of Marie removable in order to convenience operation of the device, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlincnan*, 168 USPQ 177, 179 (*MPEP 2144.04 (V-C)*).

6. Applicants further argue that the combination of references does not disclose the claimed invention because Marie does not disclose the removable fluid conduit

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and removable cap as separate elements as claimed, since the tubular connector 31 is part of the joining piece 30.

However, being part of the assembly does not preclude this part from being a separate element of the same assembly. Since the tubular connector 31 is indicated 31 and the joining piece is indicated 30, both elements are interpreted as a separate elements of the same assembly.

7. Applicants further argue that combination of Marie and Nettekoven is not a "simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement because Marie was applied for and patented after Nettekoven.

However, at the time of the instant invention has been filed both Marie and Nettekoven ware already been applied for and patented, and therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to combine Marie and Nettekoven as recited in the rejection below.

8. With respect to claims 6-8, Applicants argue that the rejection is improper because the Office Action supplies no evidence whatsoever to support a conclusion that the elements 31, 8 and 15 of Marie can be formed together as an integral component.

However, it has been held that forming in one piece an article which has formerly been formed in several pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993)(**MPEP 2144.04 (V-B)**).

9. Applicants further argue that the rejection is improper because the Office Action supplies no evidence whatsoever to support a conclusion that one of elements 31, 8 and 15 of Marie can be formed of a resilient material.

In accordance with the definition, resilience is the property of a material that enables it to resume its original shape or position after being bent, stretched, or compressed; elasticity (See The American Heritage® Dictionary of the English Language, Fourth Edition), that is an inherent property of the plastic material. Since mentioned elements have been formed of the plastic material (Marie, Col. 3, lines 52-53), the obviousness rejection is proper.

10. With respect to claims 3,4, 15, 25, 26 and 28 are substantially identical to arguments discussed above.

#### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-15 and 17-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-12 and 16-23 of copending Application No. 11/717,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '727 application claims every material limitation of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Claim Rejections – 35 USC § 103*

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

14. Claims 1, 2, 5-15, 17-24 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marie (US 6,149,622 A) in view of Nettekoven (US 5,496,270 A).
15. In Re claim 1, Marie discloses a medical vacuum aspiration device (1) comprising:
  - an aspiration cylinder (42); and
  - a valve, the valve comprising:
    - a removable fluid conduit (8, 15, 31) having a first end for attaching to the aspiration cylinder (42) and a second end for attaching to a cannula (32);

a valve housing (3, 4) having at least first and second housing portions (3, 4) that define a cavity for removably holding at least a portion of the fluid conduit (8, 15, 31);  
means (5) for removably attaching the first housing portion (3) to the second housing portion (4);  
a removable cap (30) that connects the first and second housing portions (3, 4); and  
an actuator (18, 19), coupled to the valve housing (3, 4), that selectively compresses a portion of the fluid conduit (15) to open and close a suction path defined by the fluid conduit (see figures 1-4, infra).

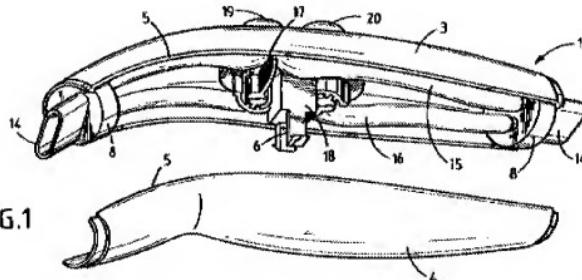


FIG.1

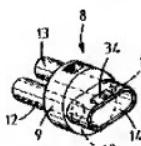


FIG.2

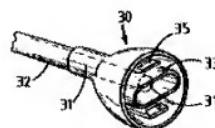


FIG.3

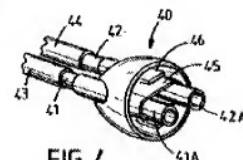


FIG.4

Maric does not disclose expressly a hinged connection of the housing portions.

Nettekoven discloses a medical irrigation device (10) with a valve housing (11) with two housing portions (12, 13) that are connected by a pivoting hinge (15)(see fig. 1 infra). The

hinged connection permits the interior of the housing to be accessed while keeping the housing portions attached to one another to avoid misplacement of one of the housing portions.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the hinged connection of Nettekoven to the aspiration device of Marie in order to permits the interior of the housing to be accessed while keeping the housing portions attached to one another.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a).

*Ex Parte Smith*, 83 USPQ2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a).

*Ex Parte Smith*, 83 USPQ2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

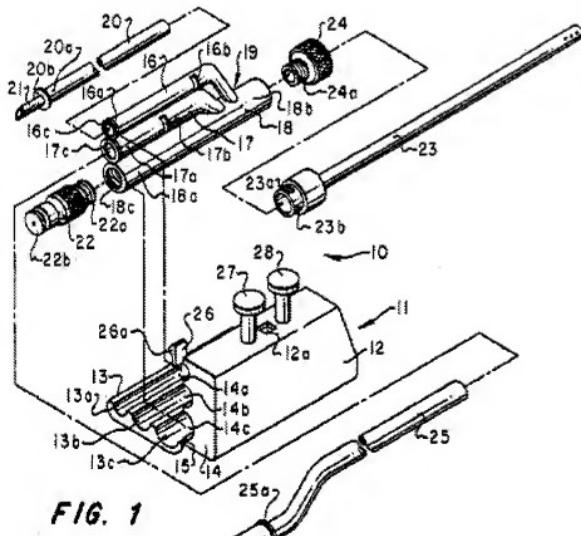


FIG. 1

16. In Re claims 5 and 13, Marie discloses a receptacle (40, 45) proximate the first end that is capable of receiving an end of the aspiration cylinder (42) to provide a sealed connection..

17. In Re claims 2, 6-8 and 14, While Marie in view of Nettekoven substantially disclose the aspiration device as instantly claimed, they do not disclose that the first and second housing portions comprise a single piece unit and that the fluid conduit and the receptacle comprise a single piece unit, as per claims 2, 6 and 14. However, in light of *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); It would have been within the skill of those skilled in the art to utilize polypropylene as a resilient plastic

conventionally utilized as a material in medical aspiration devices (see Nettekoven, col. 5, lines 24-37).

18. In Re claims 7, 8 and 27, Nettekoven discloses the use of silicone rubber in col. 3, lines 21-23.

19. In Re claim 9, Marie discloses that the housing portions (3, 4) restrain movement of the fluid conduit (8, 15) when closed (see fig. 1).

20. In Re claim 10, Marie discloses that the cap (30) connects the housing portions (3, 4) adjacent the second end of the conduit (8, 15, 31).

21. In Re claims 11 and 12, Marie discloses that a portion (31) of the fluid conduit extends outwardly from an end of the cap (30) and that the cap (30) restrains the conduit (8, 15, 31)(see fig. 3).

22. In Re claim 15, Marie discloses a conduit clamp (18)(see fig. 1).

23. In Re claim 17 Nettekoven discloses that the hinge comprises a living hinge (hinge 15 consisting of a flexure bearing with no moving parts)(see fig. 1).

24. In Re claims 18 and 19, while Nettekoven discloses a single hinge, the instant claim calls for two of them. It is well established in the art that the duplication of parts is within the skill of those skilled in the art, and as such is obvious.

25. In Re claim 20, Nettekoven teaches that the releasable connector is a releasable latch (tang 26 described in column 4, lines 21-30).

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26. In Re claim 21, Nettekoven teaches a latch tab (26) and a tab recess (12a).
27. In Re claim 22, Nettekoven discloses that the tab (26) comprises a dome portion (26a) that cooperates with the tab (12a).
28. In Re claim 23, Nettekoven discloses that the tab (26) and recess (12a) are integrally formed on one of the housing portions (12, 13).
29. In Re claim 24, Marie discloses that the cap (30) is located at one of the ends of the housing (3, 4)(see fig. 1).
30. Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Marie and Nettekoven in view of Norelli (U.S. 4,909,792).
31. In Re to claim 28, Marie and Nettekoven do not specify the presence of the aspiration syringe. However, the use of a syringe is conventional and routinely used in the art, such as disclosed in Norelli. Norelli discloses medical device/syringe that creates a vacuum within the syringe by withdrawing the plunger from the syringe body (column 4, lines 5-11) with removable fluid conduit (10) having a first end for attaching to an aspiration cylinder/plunger end (figure 6) and a second end for attaching to a needle/cannula 12 (figure 3); a safety device/valve housing (50) for any type of medical purpose (column 5, lines 43-58) having semi-cylindrical jaws/first and second housing portions 52,54 that define a cavity for removably holding at least a portion of conduit 10 (column 4, lines 56-65 and figures 3 and 5); each jaw/housing portion is connected to the barrel 56 by a hinge 58 and 60, respectively to form a single-piece unit (column 4, lines 60-65). Based on the similarity of devices and the problem to

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be solved it would have been obvious to those skilled in the art that the device of Marie and Nettekoven is connected to a syringe in order to perform the intended function.

32. Claims 3, 4, 25 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marie and Nettekoven and further in view of Moutafis *et al.* (US 7,122,017 B2; hereinafter "Moutafis").

Marie and Nettekoven do not expressly disclose polypropylene construction.

Moutafis discloses a surgical instrument with polypropylene construction (col. 32, lines 37-56).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a).

*Ex Parte Smith*, 83 USPQ2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a).

*Ex Parte Smith*, 83 USPQ2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions

resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

***Conclusion***

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/  
Examiner, Art Unit 3761

/Michele Kidwell/  
Primary Examiner, Art Unit 3761